

Notice of Allowability

Application No.

10/539,497

Examiner

Melenie McCormick

Applicant(s)

DONG, HUI

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to arguments received on 11/15/06.
2. ☒ The allowed claim(s) is/are 1-6.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

The response with amendments filed on November 15, 2006 has been received and entered.

Examiners Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Daniel Hudak Jr. on 01/22/07.

IN THE CLAIMS

Claim 1 has been re-written as

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Claim 1. A composition comprising an *Epimedium* extract preparation for use in the treatment of prostatic hyperplasia wherein the extract preparation comprises a flavones extract and polysaccharides in a ratio of from 2:8 to 8:2 by weight, respectively, of the composition, wherein flavones in the flavones extract range from 20% to 90% by weight, and the molecular weight of the extract polysaccharides ranges from 1,000 to 700,000 Daltons and wherein the composition is free of polysaccharides having a molecular weight below 1,000 Daltons.

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In claim 2 at line 2, the word "crude" has been omitted.

Also in claim 2, at line 2, "extract" has been added after "flavones".

Claim 3 has been re-written as

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Claim 3. A method of *Epimedium* herb extraction comprising the steps of:

extracting the *Epimedium* herb with a solution containing 60% to 95% by volume of an organic solvent, filtering the extract to obtain a filtrate, recovering the organic solvent from the filtrate, adding the recovered organic solvent containing the extracted *Epimedium* herb to an absorption column, subsequently washing the column with water, eluting the column with 30-85% ethanol by volume and recovering the eluent by suction filtration, collecting all the eluent and evaporating to dryness and obtaining a flavones residue, wherein flavones in the extracted flavones residue are about 20% to 90% by weight,

decocting a polysaccharides residue from the column with water and concentrating the decoction, adding a sufficient quantity of ethanol to obtain a final concentration of 70% to 85% by volume based on the total volume of the polysaccharides residue, water, and ethanol, filtering to obtain crude polysaccharides, dissolving the crude polysaccharides in water and adding a chloroform-n-butanol (3-6:1) to precipitate protein debris, removing any polysaccharides having a molecular weight below 1,000 Daltons by ultra filtration, concentrating the aqueous extract to dryness to obtain refined polysaccharides having a molecular weight of from 1,000 to 700,000 Daltons, and mixing the extracted

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flavones residue and the refined polysaccharides in a ratio of from 2:8 to 8:2 by weight, respectively.

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Claim 4 has been re-written as:

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Claim 4. The method of claim 3, wherein the extract comprises the extracted flavones residue and refined polysaccharides in a ratio from 3:7 to 6:4 by weight and wherein the organic solvent comprises ethanol, propanone, isopropyl alcohol or methanol or, combinations thereof.

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Claim 5 has been re-written as:

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Claim 5. The method of claim 4, wherein the flavones in the extracted flavones residue comprise 10-90% by weight icariin and icariin I, and wherein the molecular weight of the refined polysaccharides range from 45,00 to 620,000 Daltons.

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Claim 6 has been re-written as:

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Claim 6. The method of claim 5, wherein the ratio of extracted flavones residue to refined polysaccharides is 3:7, 4:6, 5:5, 6:4, or 7:3, respectively, and wherein the ratios can be used alone or with any pharmaceutically acceptable vehicle/ excipients.

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Conclusion

Claims 1-6 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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PRIMARY EXAMINER